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IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

v.

CIBA-GEIGY CORPORATION,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF AMICUS CURIAE OF THE ILLINOIS PHARMACISTS ASSOCIATION

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INTEREST OF THE ILLINOIS PHARMACISTS ASSOCIATION

The Illinois Pharmacists Association[1] ("IPhA") is a professional society of pharmacists having a membership of

[1] The administrative offices of the IPhA are located at Suite 400, 222 West Adams Street, Chicago, Illinois 60606.

over two thousand five hundred pharmacists engaged in all aspects of pharmacy practice and teaching throughout the State of Illinois.

The Third Circuit decision in this case grants a nationwide monopoly on the appearance characteristics of drug dosage forms which function to identify the drugs themselves. It authorizes failure to select and promote useful generic names for drugs. The decision of the Third Circuit will accordingly adversely affect drug product selection, pharmacy communication with patients and public health and safety in the State of Illinois.

The IPhA submits this brief in support of the Petition for Certiorari, pursuant to Rule 36.1 of the Rules of this Court, written consent of the parties being submitted herewith.

The IPhA's position is that the Third Circuit's Opinion in this case should be overturned to the extent that it affirmed a ruling based on a series of presumptions including the presumptions that Bolar acted in bad faith merely because it elected to manufacture a generic drug in publicly accustomed colors and that Bolar intended to facilitate illegal substitution by pharmacists.[2] Since the rejection of the "reasonable anticipation" standard by this Court in *Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982) as it applied to Section 32 of the Lanham Act, the use of the "reasonable anticipation" standard in a Section 43 Lanham Act case should also be found to be erroneous. The use of presumptions

[2] The IPhA certainly does not condone any illegal activity by any pharmacist and submission of this brief should in no way be construed as a step taken in support of or in order to facilitate any potential illegal activity.

in this case is nothing more than use of the "reasonable anticipation" standard and should consequently be rejected by this Court as inconsistent with its opinion in the *Inwood* case.

As an affiliate of the 55,000 member American Pharmaceutical Association, the IPhA has supported the policy of the American Pharmaceutical Association to oppose the granting of monopolies in the appearance of a drug dosage form, because drug appearance identifies the drug itself, not its source. The IPhA concurs with the official statement of the American Pharmaceutical Association to Congress opposing monopolies on drug product appearance:

> [C]reating a monopoly as to the appearance characteristics of a drug dosage form . . . would be expected to drastically reduce the number of multisource drug products, thereby limiting the benefits of competition for patients in the 45 states [now 49] which have laws permitting pharmacists to engage in drug product selection for the benefit of their patients. This could also have a negative impact on patient compliance with prescribed drug regimens, since patients associate drug identity with drug product appearance. Furthermore . . . [granting a monopoly on drug appearance] would exacerbate the problem of drug identification in emergency situations such as accidental poisonings" [Def. Ex. 26, Trial Record, p. 837].

In 1977, recognizing that physicians prescribe by drug "brand name" when referring to the medication itself because of habit or unfamiliarity with generic names, Illinois joined the great majority of other states by enacting its drug product selection law, Illinois Revised Statutes Chapter 111, Paragraph 4033. This statute provides that pharmacists may dispense a lower cost drug for a "brand name" prescription under specified conditions.

The overall appearance of a drug dosage form by which it is recognized and identified must be distinguished from source identification. The IPhA also strongly supports the position of the American Pharmaceutical Association that "the name, trademark, number or code" of the drug manufacturer should be used on the dosage form itself [Def. Ex. 26, Trial Record, p. 839]. In this case, the generic manufacturer Bolar prominently printed its logo and National Drug Control Identification Number twice on each capsule, and packaged its product in distinctive containers, clearly identifying itself as the manufacturer.

The opinion of the Third Circuit interferes with the valid state policy of Illinois to facilitate generic drug substitution. The availability of generic drugs promotes competition in the pharmaceutical marketplace, with the resultant effect of cost containment. The Third Circuit decision limits the pharmacist, physician and patient seeking the drug dosage form in a uniform accustomed appearance by which it is recognized, to a single, monopoly source. Requiring generic drugs to have a different physical appearance from that by which the drug has been recognized and identified by patients and health care professionals will have a serious anticompetitive impact on the generic drug industry.

ARGUMENT

A.

THE APPEARANCE CHARACTERISTICS OF A DRUG DOSAGE FORM SERVE TO IDENTIFY THE DRUG ITSELF AND SHOULD NOT BE MONOPOLIZED.

The functionality of the accustomed appearance for drug identification was properly expressed by this Court in its approval of the District Court decision in *Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982), as follows:

> . . . that the blue and blue-red colors were functional to patients as well as to doctors and hospitals: many elderly patients associate color with therapeutic effect: some patients co-mingle medications in a container and rely on color to differentiate one from another: colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs [456 U.S. 844 at 853].

This utility of the accustomed appearance characteristics of a drug dosage form, which is unrelated to identification of the manufacturer of the drug, was confirmed in the present *Ciba-Geigy v. Bolar* case by the testimony of Dr. James O'Donnell[3] [Trial Record, pp. 351-377, 422-425].

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[3] In addition to serving as a pharmacist member of the Generic Drug Technical Advisory Council of the State of Illinois and an experienced poison control specialist of the Chicago Poison Control Center, Dr. O'Donnell also presently serves as the Vice President for Professionals Affairs of the IPhA. Dr. O'Donnell did not, however, testify on behalf of the IPhA.

As pointed out by this Court in its landmark *Kellogg Co. v. National Biscuit Co.* ("Shredded Wheat") decision:

> [A] particular manufacturer can no more assert exclusive rights in a form in which the public has become accustomed to see the article and which, in the minds of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind [305 U.S. 111, 118].

This Court affirmed in *Inwood, supra*, that there can be no grant of monopoly unless the "manufacturer can show that in the minds of the public, the primary significance of a product feature or terms is to identify the source of the product rather than the product itself" *Id.* at 851. The primary significance of the appearance of a drug dosage form is drug identity, not source.

This issue was crystallized by Chief Justice Burger in his question to the Justice Department Attorney, Mr. Ganzfried, during oral argument in the *Inwood v. Ives, supra* as to the functionality of color for drug product identification as opposed to source identification:

> *Mr. Ganzfried*: For example, if I may take one that appears before me, a question of judicial robes. If there were one company that made judicial robes and made them black, would the second company that made them have to make them green? The question is do you identify the color with the product or do you identify it with the producer; and that is the issue in this case.
>
> *Question*: Well, in common human experience what would be, in your view, the reaction to people being handed green aspirin?
>
> *Mr. Ganzfried*: They would think it was something other than aspirin [Oral Argument Transcript, February 22, 1982, p. 29].

This is in fact the reaction of patients who, knowing a generic drug is being dispensed, receive a drug which they do not recognize. They think it is the wrong medicine. Forcing generic competitors sell green aspirin, or another drug of unfamiliar appearance because physicians and pharmacists may be able to convince most patients that the drug may have another appearance, is like forcing a competitor to make green judicial robes because judges can be convinced that it is still a judicial robe. It can usually be done, but it is an artificial barrier to competition.[4]

B.

A USEFUL GENERIC NAME IS REQUIRED FOR COMMUNICATION IN THE HEALTH CARE FIELD.

Brand name manufacturers have historically directed an exhaustive advertising campaign to health care professionals during the term of their patent monopoly on a drug product. They may deemphasize the generic name, or as in the present case, fail to even provide a useful generic name. As a consequence, many physicians come to identify a drug itself by the claimed "brand name" and write prescriptions accordingly.

---

[4] The District Court acknowledged that use of accustomed appearance "will facilitate generic substitution" and make the generic drug "more saleable because it makes it easier for both the doctor and pharmacist to substitute the generic drug" and that "the patient may resist such substitution" if it has an unaccustomed appearance [Petition Appendix, p. 9]. However, the District Court nevertheless based its grant of a monopoly on accustomed drug dosage form appearance by "predicat[ing] a rule of law upon an assumption that some pharmacists do and may illegally substitute generic drugs in order to make a greater profit" [Petition Appendix, p. 32]. This Court rejected in the *Inwood* case, *supra*, the "assumption that a pharmacist . . . will be unable to resist the temptation to profit from illegal activity" *Id.* 456 U.S. 844 at 856.

Congress had addressed the problem of failure to provide useful generic drug names in both the Trademark, and the Food, Drug and Cosmetic laws. Title 15 U.S.C. §1064(c) of the Lanham Trademark Act provides for cancellation of claimed trademarks which are "the common descriptive name of an article or substance", and Title 15 U.S.C. §1065(4) of the Lanham Act prevents acquisition of trademark rights in "the common descriptive name of any article or substance, patented or otherwise". In order to curb drug company failure to provide and promote useful generic drug names, and to "prevent profit when generic names cannot be remembered" [Congressional Record, Def. Ex. 31, Trial Record, pp. 952, 965, 982, 987-990], in 1962, Congress required that all prescription drug advertisements have a generic name printed in type at least half as large as that used for the claimed brand name 21 U.S.C. §352(n). Despite this requirement, none of Ciba's advertising relied on by the lower courts provides a useful generic name other than "Apresazide"; even the ingredient names are up to 20 or more times smaller than the claimed brand name "Apresazide" [Pl. Ex. 8-14, 19, Trial Record, pp. 1474-1548].

The legislatures of 49 states (including Illinois) have also sought to address the problem by adopting so-called "generic drug substitution laws" which either require or allow the dispensing pharmacist to dispense a generic drug when a "brand name" is written on the prescription, unless the physician otherwise directs.

The United States Adopted Names (USAN) Council, in cooperation with the official United States Pharmacopea, National Formulary, and the Food and Drug Administration, seeks to promote the selection and utilization of nonproprietary names for drugs:

> Teaching in pharmacy and medicine requires a common designation especially for a drug that is available from several sources, *and for combinations of two or more drugs.* Nonproprietary names greatly facilitate communication between physicians, and most journals demand their use. State formularies and hospital formularies generally use nonproprietary names as the titles of the articles recognized. A nonproprietary name is essential to the pharmaceutical manufacturer as a means of preserving his trademark rights in his brand name for the article concerned. Finally, federal law obliges the manufacturer to use the "established" nonproprietary name in his advertising, labels and brochures. [USAN and the USP Dictionary of Drug Names. USAN 1982, 1961-1981 Cumulative List, page 6; Dx. 24, Trial Record, p. 809] (emphasis supplied)

Despite this, Ciba-Geigy has provided no useful generic name for the drug in suit, other than its claimed brand name "Apresazide". Dr. O'Donnell correctly testified that a tongue-twisting listing of its ingredients—"Hydralazine Hydrochloride and Hydrochlorothiazide" is too cumbersome for use [Trial Record, pp. 353-361]. Patients certainly cannot remember these names. What name is to be used on prescription labels, and in patient communications? Ciba-Geigy's counsel acknowledged during his deposition of Dr. O'Donnell that he used "generic Apresazide because its easier than the mouthful describing the component parts" [April 21, 1982, Deposition of Dr. O'Donnell, p. 28, attached as Appendix pp. 1-2]. Ciba's own witnesses acknowledged that "Apresazide" is the common name for the drug and that physicians commonly refer to it as "Apresazide" [Trial Record, pp. 73-77, 136, 143, 147].

The Third Circuit decision frustrates the pharmaceutical and legal requirements for providing useful generic names.

Any association of drug product appearance with the name "Apresazide", where there is no other useful generic name, is an improper basis for the grant of a drug appearance monopoly. The trademark laws should not reward advertising, which fails to provide and promote a useful generic name, with a monopoly on the functional appearance characteristics of a drug dosage form.

CONCLUSION

For these reasons, the Illinois Pharmacists Association respectfully urges the Court to grant Certiorari to review the Third Circuit decision.

Respectfully submitted,

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APPENDIX

IN THE
UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION,

Plaintiff,

vs.

BOLAR PHARMACEUTICAL COMPANY, INC.,

Defendant.

Civil Action No. 82-0788 (HLS)

[1] The deposition of JAMES THOMAS O'DONNELL called by the Plaintiff for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before CATHERINE M. MROZEK, a Notary Public within and for the County of Cook, State of Illinois, and a Certified Shorthand Reporter of said state, at 1725 West Harrison Street, Chicago, Illinois, on the 21st day of April, A.D. 1982, at 2:00 p.m.

[2] PRESENT:

MESSRS. KAYE, SCHOLER, FIERMAN, HAYS & HANDLER,
(425 Park Avenue
New York, New York 10022), by:
MR. IRA SACKS,
appeared on behalf of the plaintiff;

MESSRS. FITCH, EVEN, TABIN, FLANNERY & WELSH,
(135 South LaSalle Street
Chicago, Illinois 60603), by:
MR. JOHN F. FLANNERY,
appeared on behalf of the Defendant.

REPORTED BY: CATHERINE M. MROZEK, C.S.R.

* * * * *

[27] Q. Are you aware of generic—and I'm saying generic Apresazide because it's easier than the [28] mouthful describing the component parts—of their plans to market a generic Apresazide?

A. Their meaning who, Reid-Provident?

Q. Reid-Provident.

A. No, I was not aware of that.

Q. Has anybody from Bolar made you aware that Reid-Provident intends to market a generic Apresazide in a green capsule?

MR. FLANNERY: No, that's assuming a fact not in evidence, Counsel.

MR. SACKS: Well, I'll be able to get that into evidence at the hearing.

* * * * *